VII. 510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular §807.92, the following summary of information is provided:

A. Submitted by:

Laetitia Cousin
Director of Regulatory Affairs and Quality Assurance
NuVasive, Incorporated
4545 Towne Centre Court
San Diego, California 92121
Telephone: (858) 909-1868
Fax: (858) 909-2068

JAN 15 2009

B. Device Name

Trade or Proprietary Name:	*NuVasive Surgical Mesh System*
Common or Usual Name:	Surgical Mesh
Classification Name:	Surgical Mesh
Device Class:	Class II
Classification:	§878.3300
Product Code:	FTL

C. Predicate Devices

The subject *Surgical Mesh System* is substantially equivalent to the *Surgical Mesh System* currently distributed commercially in the U.S. by NuVasive (K053215).

D. Device Description

The original *NuVasive Surgical Mesh System* consists of a series of specialized shapes and sizes of mostly flat embroidered mesh and a radiographic marker. The meshes typically contain pre-formed reinforced holes to provide secure and easy to find suture or tissue anchor locations.

E. Intended Use

The *NuVasive Surgical Mesh System* is intended to be implanted to reinforce soft tissue where weakness exists. The device is intended for one-time use.

K081377
2/2

F. Comparison to Predicate Devices

The subject device has indications for use identical to those of its predicate, and employs the same principles of operation.

G. Summary of Non-Clinical Tests

(Not Applicable).

H. Summary of Clinical Tests

(Not Applicable).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NuVasive, Inc.
% Ms. Laetitia Cousin
Senior Director, Regulatory & Clinical
Affairs and Quality Assurance
7475 Lusk Boulevard
San Diego, California 92121

JAN 15 2009

Re: K081377
Trade/Device Name: NuVasive Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: December 15, 2008
Received: December 16, 2008

Dear Ms. Cousin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081377

Indications for Use

510(k) Number (if known):_____

Device Name: NuVasive Surgical Mesh

Indications For Use:

The Surgical Mesh System is intended to be implanted to reinforce soft tissue where weakness exists. The device is intended for one-time use.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081377